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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,325

05/04/2007

Daniel Thommen

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20306

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04/09/2010

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EXAMINER

TEMPLETON, CHRISTOPHER L

ART UNIT

PAPER NUMBER

3773

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,325	<b>Applicant(s)</b> THOMMEN ET AL.	
	<b>Examiner</b> CHRISTOPHER L. TEMPLETON	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/28/09</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment***

This office action is responsive to the amendment filed on 28 December 2009. As directed by the amendment: claims 1, 2 and 4-12 have been amended, new claims 15 and 16 have been added and claim 14 was previously withdrawn. Thus, claims 1, 2 and 4-16 are presently pending in this application.

### ***Response to Amendment***

1. The previous 35 U.S.C 112 rejections on claims 1 and 10 have been removed due to the explanation provided. The objection on claims 1 and 7 have been removed.

### ***Allowable Subject Matter***

2. The indicated allowability of claim 3 is withdrawn in view of the newly discovered reference(s) to Kotula et al (WO 97/42878). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotula et al (WO 97/42878).

5. As to claim 1, Kotula discloses an implant for occluding a passage in a circulatory system (Figures 14, 15 and 18), the implant comprising a plurality of thin elongate

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members each having a first end and a second end; a first holder 310 to which the first ends of the elongate members are attached; a second holder 308 (Figure 14) to which the second ends of the elongate members are attached, the elongate members being attached to the first and second holders; a first occluding body 316 (Figure 18) being attached to the elongate members. The implant forms in a first state an elongated structure extending along a longitudinal axis (Figure 11), the implant being adapted in the first state for insertion into the circulatory system and the implant being adapted to be brought into a second state (Figures 13, 16 and 17) in the circulatory system, wherein the distance between the holders being reducible in a manner to cause the elongate members to execute a twisting motion relative to the axis to yield a plurality of generally radially extending loops forming at least one fixation structure, thereby increasing a cross-section of the occluding body and the at least one fixation structure being fixable in the second state, and wherein the implant comprises one second occluding body 316 being attached to the elongate members at a distance to the first occluding body and wherein the distance between the first and the second occluding body is reducible by reducing the distance between the two holders, wherein a fixation structure (a radially extended loop of the elongate members) is formed between the first occluding body and the first holder (Figure 18); wherein the thin elongate members have a first portion 302 being arranged between the first holder 310 and the first occluding body 316 (Figure 14 or 18), a second portion 304 being arranged between the second holder and the second occluding body 316 (Figure 18) and a third portion 306 (Figure 14) being arranged between the first and second occluding bodies.

6. As to claim 2, Kotula discloses the first and second fixation structures as being formed in the second state (Figures 13 and 17).
7. As to claim 4, Kotula discloses the first and second portions of the elongate member having approximately the same length (Figure 18).
8. As to claim 5, Kotula discloses the first, second and third portions having approximately the same length (Figure 18).
9. As to claim 6, Kotula discloses the third portions not being twisted like the first and second portions (Figure 17) (when in the second state).
10. As to claim 7, Kotula discloses in the second state the first portion forming a first fixation structure and the second portion forming a second fixation structure (Figure 17).
11. As to claim 8, Kotula discloses in the second state the third portion 306, forming a bended structure with an outer diameter having approximately the same size as the diameter of the cross-section of the first or second occluding body (Figure 17) (it is approximately the same size as applicant's figure 4).
12. As to claim 9, Kotula discloses the implant in the second state wherein the first and the second occluding body 316 have a cross-section having the same size (Figure 18).
13. As to claims 10 and 11, Kotula discloses the first and the second occluding body 316 being implicitly flexible and disk-shaped in the second state and implicitly compressed in the first state and having a circular shape (Figures 14, 15 and 18).
14. As to claim 13, Kotula discloses the elongate members having the same length (Figures 14, 15 and 18).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotula et al (WO 97/42878) in view of Freudenthal et al (WO 01/49785) and further in view of Solymar (U.S. Publication No. 2003/0149463).

17. As to claim 12, Kotula discloses the claimed invention except for the elongate members extending through holes of the occluding body. Freudenthal discloses using a membrane 8 on both sides of an implant for a sealing effect (page 14, line 25-page 15, line 2). Solymar teaches elongate members extending through holes of an occluding body in Figures 11-13. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implant of Kotula to include the membrane of Freudenthal for a sealing effect, and elongate members extending through the occluding body for the purpose of better securing of the occluding member to the elongate members.

18. As to claim 15, Kotula discloses the claimed invention except for thickened portions arranged on both sides of the first and second occluding bodies. Freudenthal discloses using a membrane 8 on both sides of an implant for a sealing effect (page 14, line 25-page 15, line 2). Solymar teaches thickened portions arranged on both sides of

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an occluding body for the purpose of capturing and mounting the occluding body (paragraph 49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implant of Kotula to include the membrane of Freudenthal for a sealing effect, and thickened portions on the elongate members for the purpose of capturing and mounting the occluding body in order to prevent the occluding member from moving.

19. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kotula et al (WO 97/42878) in view of Chanduszko (U.S. Publication No. 2005/0043759). Kotula discloses the claimed invention but is silent on a locking mechanism to hold the first and second holders together. Chanduszko teaches a locking mechanism to hold first and second holders together (Figures 7A-7C) for securing the implant in the deployed state (paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kotula to include a locking mechanism, as taught by Chanduszko, for the purpose of locking the implant in the deployed state to prevent it from inadvertently returning to the first state.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie T. Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./  
Examiner, Art Unit 3773

/Julian W. Woo/  
Primary Examiner, Art Unit 3773